510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K230878

B Applicant

Ad Astra Diagnostics, Inc.

C Proprietary and Established Names

QScout Lab; QScout RLD

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
GKZ	Class II	21 CFR 864.5220 - Automated Differential Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of a new device

B Measurand:

White blood cell count (WBC), Neutrophils (NEUT#), Lymphocytes (LYMPH#), Monocytes (MONO#), Eosinophils (EOS#), Basophils (BASO#), Immature Granulocytes (IG#), Percent Neutrophils (NEUT%), Percent Lymphocytes (LYMPH%), Percent Monocytes (MONO%), Percent Eosinophils (EOS%), Percent Basophils (BASO%), Percent Immature Granulocytes (IG%), Neutrophil to Lymphocyte Ratio (NLR)

C Type of Test:

Quantitative complete blood count (CBC) with 6-part differential: WBC, NEUT#, LYMPH#, MONO#, EOS#, BASO#, IG#, NEUT%, LYMPH%, MONO%, EOS%, BASO%, IG%, NLR

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The QScout Lab is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations 18 years and older found in clinical laboratories and point-of-care (POC) settings. The QScout Lab is used with the QScout RLD test to enumerate and classify the following parameters in venous K2/K3EDTA whole blood : White blood cell count (WBC), Neutrophils (NEUT#), Lymphocytes (LYMPH#), Monocytes (MONO#), Eosinophils (EOS#), Basophils (BASO#), Immature Granulocytes (IG#), Percent Neutrophils (NEUT%), Percent Lymphocytes (LYMPH%), Percent Monocytes (MONO%), Percent Eosinophils (EOS%), Percent Basophils (BASO%), Percent Immature Granulocytes (IG%), Neutrophil to Lymphocyte Ratio (NLR)

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

D Special Instrument Requirements:

QScout Lab

IV Device/System Characteristics:

A Device Description:

The QScout system is intended for in vitro diagnostic use in screening patient populations found in clinical laboratories and point-of-care (POC) settings. The QScout system is a quantitative multi-parameter automated hematology analyzer that provides results for complete blood count (CBC) parameters with a 6-part differential. It includes the QScout Lab analyzer, the QScout RLD (Rapid Leukocyte Differential) test, software, and handheld barcode scanner. The QScout Lab is a tabletop automated hematology analyzer operated through a touch screen interface. The QScout RLD test package contains the reagents to run the test and the port to which the blood sample is dispensed. The system is supplied with a Barcode Scanner and stand for the scanner. The QScout system reports white blood cell count and neutrophil to lymphocyte ratio and enumerates and classifies six white blood cell types including neutrophils, lymphocytes, monocytes, eosinophils, basophils, and immature granulocytes.

B Principle of Operation:

The QScout RLD test includes a microfluidic chamber of predetermined volume containing a dried reagent of organic compounds to stain and fluoresce white blood cells. Venous whole

blood is transferred manually using a pipette capable of transferring 10µL to the QScout RLD test where cells mix with the reagent. The QScout RLD test is inserted into the QScout Lab, a quantitative multi-parameter automated hematology analyzer, where an optical imaging system takes images of the test chamber. A fixed (locked) machine vision algorithm identifies cells from the images in real time. When analysis is complete, the results are displayed on the screen and can be printed.

C Instrument Description Information:

1. Instrument Name:

   QScout Lab

2. Specimen Identification:

   Specimen identification is performed by manual keyboard entry or use of a barcode reader.

3. Specimen Sampling and Handling:

   The QScout system can be used with venous anticoagulated whole blood samples collected in K_2EDTA or K_3EDTA tubes. Venous whole blood samples are collected into K_2EDTA or K_3EDTA tubes using each user facility's standard procedure. Venous whole blood should be sufficiently mixed and stored at room temperature for less than three (3) hours before use. Venous whole blood is transferred manually using a pipette capable of transferring 10 µL.

4. Calibration:

   The QScout Lab device is factory calibrated prior to shipping to the end user, and no further calibration is needed.

5. Quality Control:

   QScout BCS Control is a three-level biological quality control solution which is available to monitor system performance over time. This includes low, normal, and high levels prepared from bovine and porcine leukocytes with human erythrocytes suspended in a plasma-like solution. The biological controls are run every seven (7) days.

   A two-level synthetic bead control solution is available to monitor counting capability and optical system performance metrics of the QScout Lab analyzer. The synthetic controls should be run weekly.

   Both quality control types are produced by AAD, who can be contacted to order replacements.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Beckman Coulter UniCel DxH 800 Coulter Cellular Analysis System

B Predicate 510(k) Number(s):
K140911

C Comparison with Predicate(s):

Device & Predicate Device(s):	K230878	K140911
Device Trade Name	QScout Lab, QScout RLD	Beckman Coulter UniCel DxH 800 Coulter Cellular Analysis System
General Device Characteristic Similarities		
Intended Use/Indications For Use	The QScout Lab is a quantitative multi-parameter automated hematology analyzer intended for in vitro diagnostic use in screening patient populations found in clinical laboratories and point-of-care (POC) settings. The QScout Lab is used with the QScout RLD test to enumerate and classify the following parameters in venous K2/K3EDTA whole blood: • White blood cell count (WBC) • Neutrophils (NEUT#) • Lymphocytes (LYMPH#) • Monocytes (MONO#) • Eosinophils (EOS#) • Basophils (BASO#) • Immature Granulocytes (IG#) • Percent Neutrophils (NEUT%)	The UniCel DxH 800 Analyzer is a quantitative multi-parameter, automated hematology analyzer for in vitro diagnostic use in screening patient populations found in clinical laboratories. The UniCel DxH 800 Analyzer identifies and enumerates the parameters indicated below on the following sample types: • Whole Blood (Venous and Capillary) – WBC, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, RDW-SD, PLT, MPV, NE%, NE#, LY%, LY#, MO%, MO#, EO%, EO#, BA%, BA#, NRBC%, NRBC#, RET%, RET#, MRV, IRF • Pre-Diluted Whole Blood (Venous and Capillary) – WBC, RBC, HGB, HCT, MCV, MCH, MCHC,

	• Percent Lymphocytes (LYMPH%) • Percent Monocytes (MONO%) • Percent Eosinophils (EOS%) • Percent Basophils (BASO%) • Percent Immature Granulocytes (IG%) • Neutrophil to Lymphocyte Ratio (NLR)	RDW, RDW-SD, PLT, MPV • Body Fluids (cerebrospinal, serous and synovial) – TNC and RBC
Regulation	21 CFR 864.5220	Same
Product code / class	GKZ	Same
Target population (age)	Adults only (18 and up)	Pediatric and Adults
Specimen type	Venous whole blood (K2, K3 EDTA)	Capillary and venous whole blood; diluted whole blood; body fluids (CSF, serous, synovial)
Quality Control	3 Level Biological Controls 2 Level Synthetic Controls	3 Level Whole Blood Control Electrical processing/ flow rate Control
General Device Characteristic Differences		
Intended Use sites	Clinical and POC	Clinical lab only
Test Principle	White blood cells are stained within a microfluidic chamber and scanned with an optical imaging system. Each image is analyzed by a machine vision algorithm to count and differentiate the white blood cells.	1. Coulter principle of automated cell counting and sizing. 2. Photometric measurement of HgB. 3. VCSn technology for WBC differential, NRBC, and RET. Cells are mixed with reagent and the prepared sample is delivered to a flow cell where light scatter, cell volume, and cell conductivity are measured.
Throughput	25 samples/hour	>72 samples/hour

Sample Volume	10µL (manual)	165µL (automated; aspiration volume)
Calibration	Factory Calibrated	As needed by the operator

VI Standards/Guidance Documents Referenced:

- IEC 60601-1-2:2007, Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance Collateral Standard: Electromagnetic Compatibility
- CLSI H20-A2 (2007): Reference Leukocyte (WBC) Differential Count (Proportional) and
- Evaluation of Instrumental Methods; Approved Standard—Second Edition
- CLSI H26-A2 (2010): Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition
- CLSI EP17-A2 (2012): Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP07 (2018): Interference Testing in Clinical Chemistry; Approved Guideline – Third Edition
- CLSI EP09-c (2018): Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition
- CLSI EP05-A3 (2014): Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition
- CLSI EP06-A2 (2020): Evaluation of the Linearity of Quantitative Measurement Procedures; Approved Guideline – Second Edition
- CLSI EP28-A3c (2010): Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition
- CLSI EP25-A (2009): Evaluation of Stability of In Vitro Diagnostic Reagents; Approved
- Guideline – First Edition
- CLSI EP37 (2018): Supplemental Tables for Interference Testing in Clinical Chemistry; Approved guideline – First Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision:

a) Repeatability: The study was conducted at two (2) POC sites with six (6) operators using 31 K3EDTA or K2EDTA venous whole blood samples over 19 days with four (4) QScout Lab analyzers. Samples were tested 20 times for all parameters. Results were obtained within 3 hours of sample collection. For each reported parameter and for each sample tested, the mean, SD, and %CV were calculated along with the 95% CI of the SD and %CV. The study met the pre-defined acceptance criteria for all parameters.

Parameter	WBC Range	N Samples	N Replicates	Mean	Pooled SD	Pooled CV%

WBC $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	1.55	0.08	6.07
	WBC≥4 $x10^3/\mu L$	19	20 - 31	10.84	0.42	3.64
NEUT# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.79	0.05	15.05
	WBC≥4 $x10^3/\mu L$	19	20 - 31	7.36	0.33	4.22
LYMPH# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.54	0.05	11.45
	WBC≥4 $x10^3/\mu L$	19	20 - 31	2.06	0.13	6.01
MONO# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.17	0.02	25.17
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.93	0.08	9.87
EOS# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.03	0.01	N/A
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.11	0.02	28.14
BASO# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.01	0.01	N/A
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.03	0.01	N/A
IG# $x10^3/\mu L$	WBC<4 $x10^3/\mu L$	12	21 - 31	0.02	0.01	N/A
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.34	0.07	33.42
NEUT%	WBC<4 $x10^3/\mu L$	12	21 - 31	42.89	2.31	13.21
	WBC≥4 $x10^3/\mu L$	19	20 - 31	65.13	1.31	2.34
LYMPH%	WBC<4 $x10^3/\mu L$	12	21 - 31	41.69	2.37	8.84
	WBC≥4 $x10^3/\mu L$	19	20 - 31	21.78	0.80	5.22
MONO%	WBC<4 $x10^3/\mu L$	12	21 - 31	11.90	1.94	23.54
	WBC≥4 $x10^3/\mu L$	19	20 - 31	8.87	0.81	8.82
EOS%	WBC<4 $x10^3/\mu L$	12	21 - 31	1.69	0.54	80.58
	WBC≥4 $x10^3/\mu L$	19	20 - 31	1.09	0.24	28.26
BASO%	WBC<4 $x10^3/\mu L$	12	21 - 31	0.66	0.45	93.77
	WBC≥4 $x10^3/\mu L$	19	20 - 31	0.42	0.12	N/A
IG%	WBC<4 $x10^3/\mu L$	12	21 - 31	1.17	0.69	67.87
	WBC≥4 $x10^3/\mu L$	19	20 - 31	2.70	0.59	31.95
NLR	WBC<4 $x10^3/\mu L$	12	21 - 31	2.49	0.56	18.48
	WBC≥4 $x10^3/\mu L$	19	20 - 31	6.15	0.62	6.21

b) Reproducibility: The study was conducted at three (3) sites (2 POC and 1 clinical lab), over five (5) days with two (2) runs per day and three (3) replicates per run using QScout BCS Hematology Control (a 3-level control set) comprising low, normal and high levels of measurands. Throughout the study, three (3) QScout Lab analyzers and six (6) lots of the QScout RLD test cartridges were utilized by a total of eight (8) operators. The data was used to calculate between-day, between-run, between-site (includes variability of different systems and operators), and reproducibility (total precision), using a nested ANOVA model for statistical analysis. For each reported parameter and for each level of control tested, the mean, SD and %CV were calculated. All components of calculated variation met the pre-defined acceptance criteria.

				Within Run		Between Run		Between Day		Between Lot		Between Site		Reproducibility	
Parameter x10^3/µL or %	**Control Level**	**Mean Value**	**N**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
WBC	Low	3.17	180	0.15	4.69	0.04	1.20	0.00	0.00	0.04	1.23	0.08	2.59	0.18	5.54
	Normal	8.02	180	0.28	3.48	0.26	3.24	0.08	0.95	0.00	0.00	0.14	1.68	0.41	5.10
	High	20.90	180	0.78	3.71	0.40	1.92	0.00	0.00	0.23	1.08	0.23	1.10	0.93	4.45
NEUT#	Low	1.52	180	0.09	6.20	0.00	0.00	0.00	0.00	0.03	1.84	0.02	1.12	0.10	6.45
	Normal	4.64	180	0.19	3.99	0.14	2.95	0.04	0.86	0.00	0.00	0.07	1.44	0.24	5.23
	High	13.22	180	0.59	4.46	0.22	1.63	0.04	0.30	0.15	1.15	0.12	0.87	0.66	4.98
LYMPH#	Low	1.09	180	0.08	6.88	0.04	3.21	0.02	1.83	0.00	0.00	0.04	3.85	0.10	8.66
	Normal	1.89	180	0.11	5.68	0.09	4.87	0.03	1.75	0.00	0.00	0.08	4.18	0.17	8.62
	High	3.17	180	0.17	5.44	0.13	4.10	0.04	1.36	0.00	0.00	0.09	2.87	0.24	7.44
MONO#	Low	0.35	180	0.04	12.68	0.01	3.14	0.00	0.57	0.01	2.29	0.03	8.57	0.06	15.79
	Normal	0.59	180	0.05	8.53	0.02	2.54	0.01	2.03	0.02	3.90	0.03	4.41	0.06	10.80
	High	1.10	180	0.09	7.88	0.04	4.00	0.00	0.00	0.00	0.00	0.08	7.00	0.12	10.91
EOS#	Low	0.14	180	0.02	16.17	0.01	7.14	0.00	0.00	0.00	0.00	0.00	0.00	0.03	18.27
	Normal	0.67	180	0.08	11.45	0.00	0.00	0.00	0.00	0.02	2.39	0.02	2.39	0.08	11.86
	High	2.62	180	0.25	9.70	0.03	1.07	0.00	0.00	0.06	2.14	0.03	0.95	0.26	9.91
BASO#	Low	0.03	180	0.01	39.89	0.00	10.00	0.00	3.33	0.00	0.00	0.00	6.67	0.01	42.28
	Normal	0.14	180	0.03	22.82	0.01	9.29	0.00	0.00	0.01	9.29	0.02	10.71	0.04	27.80
	High	0.52	180	0.08	14.47	0.00	0.00	0.00	0.00	0.03	4.81	0.02	4.04	0.08	15.60
IG#	Low	0.04	180	0.01	31.63	0.00	0.00	0.00	0.00	0.00	10.00	0.00	10.00	0.01	35.26
	Normal	0.10	180	0.03	27.14	0.01	13.00	0.00	0.00	0.00	0.00	0.02	20.00	0.04	35.82
	High	0.27	180	0.06	20.71	0.02	8.89	0.00	0.00	0.02	7.04	0.06	20.37	0.09	30.89
NEUT%	Low	48.06	180	1.74	3.62	0.78	1.62	0.47	0.97	0.00	0.00	0.78	1.61	2.11	4.36
	Normal	57.81	180	1.35	2.34	0.23	0.40	0.32	0.55	0.00	0.00	0.25	0.44	1.43	2.44
	High	63.25	180	1.45	2.29	0.14	0.22	0.40	0.63	0.00	0.00	0.00	0.00	1.51	2.40
LYMPH%	Low	34.49	180	1.65	4.79	0.57	1.66	0.59	1.71	0.00	0.00	0.46	1.34	1.90	5.48
	Normal	23.51	180	1.01	4.31	0.58	2.45	0.27	1.14	0.00	0.00	0.57	2.43	1.33	5.54
	High	15.18	180	0.67	4.44	0.44	2.87	0.24	1.56	0.00	0.00	0.28	1.83	0.88	5.65
MONO%	Low	10.96	180	1.39	12.70	0.00	0.00	0.08	0.68	0.25	2.32	0.65	5.90	1.56	14.21
	Normal	7.39	180	0.62	8.35	0.20	2.65	0.11	1.46	0.20	2.68	0.22	3.02	0.72	9.75
	High	5.24	180	0.42	8.08	0.15	2.90	0.11	2.12	0.00	0.00	0.31	5.84	0.56	10.42
EOS%	Low	4.47	180	0.69	15.43	0.23	5.08	0.00	0.00	0.00	0.00	0.12	2.60	0.74	16.62
	Normal	8.31	180	0.86	10.31	0.00	0.00	0.00	0.00	0.24	2.83	0.35	4.20	0.95	11.40
	High	12.53	180	1.08	8.65	0.00	0.00	0.14	1.13	0.20	1.60	0.14	1.11	1.12	9.06
BASO%	Low	0.87	180	0.33	37.51	0.11	12.76	0.04	4.37	0.00	0.00	0.10	10.80	0.36	41.29
	Normal	1.70	180	0.37	21.72	0.15	8.53	0.00	0.00	0.16	9.24	0.22	12.88	0.48	27.22
	High	2.48	180	0.35	14.04	0.03	1.37	0.00	0.00	0.10	4.15	0.13	5.36	0.39	15.67
IG%	Low	1.15	180	0.37	32.00	0.00	0.00	0.02	1.91	0.13	10.87	0.13	11.48	0.41	35.76
	Normal	1.28	180	0.34	26.18	0.13	10.08	0.00	0.00	0.00	0.00	0.25	19.53	0.44	34.21
	High	1.31	180	0.27	20.82	0.11	8.63	0.03	2.52	0.08	6.11	0.28	21.53	0.42	32.02
NLR	Low	1.40	180	0.11	7.48	0.05	3.57	0.04	2.86	0.00	0.00	0.04	3.07	0.13	9.10
	Normal	2.47	180	0.14	5.72	0.09	3.48	0.05	1.82	0.00	0.00	0.07	2.87	0.19	7.32
	High	4.18	180	0.20	4.85	0.14	3.37	0.09	2.03	0.00	0.00	0.09	2.13	0.28	6.36

2. Linearity: Linearity was determined for WBC using venous K2EDTA whole blood. A linearity panel of 10 concentrations were tested between 8 to 14 times. The weighted least squares (WLS) analysis was used to assess linearity. Linearity was established between a range of 0.5 to 60 x10^3/µL for WBC.

3. Analytical Specificity/Interference: Interference studies for glucose, hemolysate, lipemia (triglyceride-rich lipoproteins), conjugated bilirubin, unconjugated bilirubin, total protein, and thrombocytosis were performed on the QScout system, using prepared low-normal and high-normal WBC concentration samples collected from healthy donor whole blood in K2EDTA or K3EDTA anticoagulated vacutainer tubes. Samples were tested in five to ten (5–10) replicates on one of three analyzers using three (3) RLD test lots. The difference from control was deemed acceptable if it was ≤ 10%.

   The results of the interference studies demonstrated for WBC that:
   - There was no significant glucose interference up to a concentration of 1000 mg/dL.
   - There was no significant hemolysate interference up to a concentration of 1000 mg/dL.
   - There was no significant lipemia interference up to a concentration of 1500 mg/dL.
   - There was no significant conjugated bilirubin interference at a concentration of 40 mg/dL.
   - There was no significant unconjugated bilirubin interference up to a concentration of 20 mg/dL.
   - There was no significant total protein interference up to a concentration of 12.3 g/dL.
   - There was no significant thrombocytosis interference up to a concentration of 750 x 10^3 platelets/µL.

   Nucleated Red Blood Cells (nRBCs): For nRBCs the QScout system raises a flag in the presence of NRBCs ≥ 0.56 per 100 WBC. At levels lower than the threshold, there is no interference with WBC differential parameters. For levels above the threshold, nRBC is flagged and excluded from the WBC differential.

4. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   a) Sample Stability: Sample stability was determined with 11 freshly collected venous normal and abnormal blood samples. The venous blood samples were collected into K_2EDTA or K_3EDTA tubes and analyzed immediately (within one hour, baseline). The samples were subsequently kept at room temperature (20–25°C) and were analyzed again, with seven to nine (7–9) replicates at timepoints 2, 3, 4, 5, and 6 hours. The data supports a sample stability claim of three (3) hours at room temperature.

   b) QScout RLD Shelf-Life Stability: Six (6) lots of QScout RLD tests were stored out of direct sunlight at 18-32°C in heat-sealed mylar packaging with testing at 2-week, 4-week, and 2-, 3-, 6-, 9-, 12-, 15-, 18-, and 19-month timepoints. At each timepoint, four (4) replicates each of a three-level biological control (low, normal, high) were run on one (1) QScout Lab analyzer for each of the six QScout RLD test lots. The study is ongoing, and the current data supports a shelf-life stability of 1 month.

   c) Transport Stability: One (1) QScout RLD test lot underwent conditioning to simulate transport in accordance with ASTM D7386 and temperature cycling. This involved exposing QScout RLD tests to hazards occurring during transport, such as manual handling, vibration, and altitude in accordance with ASTM D7386. RLD test lot then

underwent temperature cycling where the test lot was at room temperature then three (3) days at 38°C followed by 24 hours at 18°C and finally at room temperature to simulate the temperatures expected during shipment. The test kit maintained functionality and expected analytical results during shipment.

d) QScout RLD In-Use Stability: The study was conducted to establish in-use stability of the QScout RLD test when the QScout RLD test is removed from the storage box and stored at the recommended storage conditions. Two (2) lots of RLD tests were tested. Each test lot was stored at 18–32°C and tested at 0, 1, 2, 3, 4, 5, and 6 days, and then evaluated using venous whole blood samples collected in K2EDTA or K3EDTA tubes. The data supports the in-use stability for RLD tests for five (5) days.

e) QScout BCS Control Shelf-life stability: Three (3) levels (low, normal, high) were stored at 2–8°C. Three (3) lots were evaluated with two (2) replicates per level per lot of BCS control on one QScout Lab at defined timepoints. The study supports 105 days of shelf-life stability for QScout BCS Control stored upright at 2–8°C.

f) QScout BCS Control In-Use stability: Four (4) replicates of each control level (3 levels-low, normal, high) were measured on a single QScout Lab using a single lot of QScout RLD at 0, 4, 7, 11, 14, and 15 days. The study supports 14 days of in-use stability for QScout BCS Control.

g) Calibration Traceability: The QScout Lab WBC calibration process used the Beckman Coulter Z2 particle counter as the reference instrument. The calibration process assigns a reference value (R) to a fresh whole blood sample in the normal WBC range of 4.0 – 12.0 $x10^3/\mu L$. In parallel, the whole blood samples were run on four (4) QScout Lab analyzers with 30 replicates and the mean WBC is calculated of which the value is being adjusted by calibration (C). The mean calibration factor across the three fresh whole blood samples is applied to the QScout Lab. The calibration traceability met the acceptance criteria that all $calEntry$ values must be within +/-5% of $calEntrymean$. Calibration stability is ongoing and will be evaluated over 5 years. Testing will be conducted on Day 0, at months 1, 2, and 3 after Day 0, and then quarterly up to the first quarter of the sixth year. The current data provided is for 1 month and supports stability < 1 month.

5. Detection Limit: The Limit of blank (LoB), Limit of detection (LoD), and limit of quantitation (LoQ) for WBC was determined.

   The LoB was determined using five (5) plasma samples assayed six times (6x) on two (2) QScout Lab devices using two (2) QScout RLD lots for a total of 60 measurements for each lot. The LoB for WBC was determined to be 0.02 $x10^3/\mu L$.

   LoD was determined using five (5) low level samples from K3EDTA venous whole blood. Each of the prepared samples was assayed six times (6x) on each of the two (2) QScout Lab devices using two (2) QScout RLD lots for a total of 60 measurements for each lot. The LoD for WBC was determined to be 0.08 $x10^3/\mu L$.

LoQ for was determined using four (4) low level samples from native venous whole blood. Each of the prepared samples was assayed five times (5x) on each of the two (2) QScout Lab devices using two (2) QScout RLD lots for a total of 40 measurements for each lot. The LoQ for WBC was determined to be 0.38 $x10^3/\mu L$.

6. Assay Cut-Off:

   Not Applicable.

7. Accuracy (Instrument):

   Refer to Method Comparison with Predicate Device below.

8. Carry-Over:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:
   A method comparison study was performed at one (1) clinical laboratory site and seven (7) point-of-care (POC) sites with 396 venous blood specimens collected in K_2EDTA or K_3EDTA tubes. The study included normal and pathological samples to assess the QScout Lab/RLD system performance across the analytical measurement ranges (AMRs) as well as at medical decision points. Samples were obtained from patient >18 years of age with 12 of the 396 samples contrived to cover the entire AMR. The pathological samples included the following conditions: allergic reaction, anemia, autoimmune / rheumatological diseases, B12 or folate deficiency, bacterial infection, cardiovascular diseases, chronic inflammation, hemoglobinopathies / hereditary RBC diseases, iron deficiency, acute and chronic leukemias (lymphocytic or myelocytic), lymphoma, liver disease, myelodysplastic syndromes, respiratory diseases, severe trauma or bleeding due to surgery or childbirth, solid tumor or other oncological conditions, and viral infections. Each blood sample was analyzed in singlet on the QScout Lab /RLD and in duplicate on the Beckman Coulter UniCel DxH 800 (manual microscopy for IGs), but only the first replicate results was used for all data analyses. Bias was determined based on the results of the Bland-Altman regression model. For the regression analysis with 95% confidence intervals (CI) Deming (IG#) and Passing-Bablok (all others) regression were used to determine by all sites combined. All results were within the pre-defined acceptance criteria.

   Regression Analysis – All sites combined

Parameter $10^3/\mu L$ or %	N	Sample range	Slope (95% CI)	Intercept (95% CI)	Pearson's r
WBC	396	0.51 - 59.45	1.008 (0.998, 1.020)	0.020 (-0.033, 0.087)	0.996
NEUT#	396	0.00 - 45.87	0.976 (0.963, 0.987)	0.078 (0.040, 0.125)	0.985

Parameter $10^3/\mu L$ or %	N	Sample range	Slope (95% CI)	Intercept (95% CI)	Pearson's r
LYMPH#	396	0.08 - 41.15	1.036 (1.018, 1.053)	-0.004 (-0.027, 0.018)	0.972
MONO#	396	0.00 - 13.06	1.100 (1.050, 1.146)	-0.007 (-0.030, 0.015)	0.907
EOS#	396	0.00 - 1.82	0.900 (0.867, 0.995)	0.010 (0.004, 0.017)	0.883
BASO#	396	0.00 - 1.61	0.720 (0.644, 0.861)	0.010 (0.010, 0.010)	0.922
IG#	139	0.00 - 7.55	1.194 (1.004, 1.538)	-0.003 (-0.011, 0.003)	0.926
NEUT%	396	0.3 - 96.0	0.954 (0.939, 0.968)	1.830 (0.882, 2.860)	0.981
LYMPH%	396	0.7 - 99.0	0.983 (0.968, 0.997)	0.719 (0.430, 1.018)	0.979
MONO%	396	0.0 - 75.1	0.985 (0.931, 1.033)	0.603 (0.264, 1.008)	0.928
EOS%	396	0.0 - 25.3	0.897 (0.860, 0.929)	0.129 (0.092, 0.200)	0.949
BASO%	396	0.0 - 4.9	0.889 (0.800, 1.000)	-0.056 (-0.100, 0.000)	0.690
IG%	139	0.0 - 21.5	0.862 (0.713, 1.010)	0.471 (0.272, 0.671)	0.896
NLR	396	0.00 - 120.71	0.914 (0.891, 0.934)	0.089 (0.060, 0.146)	0.947

2. Matrix Comparison:

The matrix comparison study was conducted to assess the comparison of K_3EDTA venous whole blood and K_2EDTA venous whole blood on the QScout Lab. A total of 40 paired patient venous whole blood samples were collected from each participant. The study was conducted with one (1) replicate per sample at three (3) sites with trained operators. Weighted Deming regression analysis was performed, and results were within the pre-defined acceptance criteria, demonstrating the equivalency between K_2EDTA and K_3EDTA whole blood.

D Clinical Studies:

1. Clinical Sensitivity:

The WBC flagging capability was evaluated for QScout by comparing to the WBC differential results obtained by the microscopic 400-cell manual differential reference method (2 slides/200 cells counted per slide) for 100 samples qualified as normal and 100 samples of various abnormalities. The study was conducted by trained operators. Three blood film slides

were prepared for each sample for manual measurement. Two types of abnormalities were evaluated: (1) distributional abnormal samples, which are samples where the quantity of at least one of the parameters resides outside of the normal concentrations, and (2) morphological abnormal samples, which includes atypical cell features, blasts, nucleated red blood cells (NRBC), and atypical/variant lymphocytes contained in ordinary blood samples. Overall agreement, sensitivity, and specificity were calculated with 95% confidence intervals for distributional flagging, morphological flagging, and overall flagging performance.

Overall WBC Flagging, QScout versus Bloor Smear

	Overall Agreement % (95% CI)	**Sensitivity % (95% CI)**	**Specificity % (95% CI)**
Distributional Flagging	87.00 (81.53, 91.33)	87.88 (79.78, 93.58)	86.14 (77.84, 92.21)
Morphological Flagging	97.50 (94.26, 99.18)	81.25 (54.35, 95.95)	98.91 (96.13, 99.87)
Overall Flagging	87.00 (81.53, 91.33)	88.00 (79.98, 93.64)	86.00 (77.63, 92.13)

2. Clinical Specificity:

   Refer to Clinical Sensitivity above.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   Not Applicable.

E Clinical Cut-Off:

Not Applicable.

F Expected Values/Reference Range:

A reference interval study was conducted to establish adult reference intervals for all QScout system parameters. The study was performed using venous whole blood samples collected from 265 (139 female and 126 male) apparently healthy adults (≥ 18 years) at six (6) sites. Five (5) QScout Labs, 24 RLD test lots, and eight (8) operators were used in the study. The lower and upper limits of the 95% reference intervals were determined based on the 2.5th and 97.5th percentiles of measurements for each sex group, respectively.

Parameter	Female n=139	Male n=126
WBC $x10^3$ /µL	4.00–11.30	3.78–12.12
NEUT# $x10^3$ /µL	1.68–7.42	1.56–7.89
LYMPH# $x10^3$ /µL	1.25–3.98	1.08–3.92
MONO# $x10^3$ /µL	0.27–0.92	0.25–1.08
EOS# $x10^3$ /µL	0.04–0.61	0.03–0.76
BASO# $x10^3$ /µL	0.01–0.11	0.01–0.16
IG# $x10^3$ /µL	0.00–0.04	0.00–0.06
NEUT%	33.8–71.4	33.7–75.0
LYMPH%	19.2–54.0	15.6–55.7
MONO%	4.8–13.2	4.6–13.1
EOS%	0.4–8.1	0.5–7.2
BASO%	0.2–1.5	0.1–2.2
IG%	0.0–0.5	0.0–0.7
NLR	0.63–3.76	0.62–4.89

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.